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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,109	12/02/1999	MARK R. PRAUSNITZ	GTRC-2139	2183

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EXAMINER

KREMER, MATTHEW J

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 03/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/453,109

Applicant(s)

PRAUSNITZ ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-4, 6, 10, 27, 29-30, 36, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent Application Publication JP07132119A to Yoshihiko (cited by Applicant). Yoshihiko discloses a blood-collecting device that includes a substrate 1 with a plurality of microneedles 11 and a collection chamber (where the number 12 is located). The length of the microneedles is 495 microns which is about 500 microns. (paragraphs 0014-0015 of Yoshihiko). The diameter or width of

the microneedles is 30 microns. (paragraph 0018 of Yoshihiko). The microneedles are perpendicular to the substrate. (Fig. 2 of Yoshihiko). In regard to claims 2-4 and 6, a means for inducing flow is disclosed. (paragraph 0009 of Yoshihiko). The membrane 12 is deformed when heat is generated from the micro-heater 3 which increases the volume of the collection chamber. In claims 3 and 29, the blood is collect by a negative pressure in the collection chamber as stated in lines 9-10 of the constitution of Yoshihiko. In regard to claim 30, the device sucks up blood which inherently includes glucose, cholesterol, and hemoglobin. (paragraph 0007 of Yoshihiko). In regard to claim 36, the device is applied to the skin surface of a human being. (paragraph 0021 of Yoshihiko).

3. Claims 1-2, 9-23, 25-28, 31-32, 35, and 37-46 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,334,856 to Allen et al. Allen discloses a microneedle device that can be used for the controlled sampling of biological fluid in a minimally-invasive manner. (column 2, lines 55-58 of Allen et al.). The microneedles have a width that is between 10 nm to 1 mm, preferably between 10-100 microns. (column 5, lines 38-549 of Allen et al.). The microneedles have a length between 1 micron and 1 mm, preferably between 30-200 microns. (column 5, lines 51-58 of Allen et al.). The device includes a substrate to which the microneedles are attached or integrally formed and a reservoir. (column 4, lines 33-38 of Allen et al.). In regard to claims 2 and 12, the transportation of molecules through the microneedles can be controlled using various combinations of valves, pumps, sensors, actuators, and

microprocessors. (column 7, lines 4-12 of Allen et al.). In regard to claim 9, the device may have a plurality of compartments. (column 8, lines 52-65 of Allen et al.). In regard to claim 10, Fig. 1B of Allen et al. shows a 3D array of microneedles. In regard to claim 11, an adhesive layer is used to facilitate contact with the biological barrier. (column 8, lines 41-49 of Allen et al.). In regard to claims 14-15, 18, and 22, a biosensor in the collection chamber or in the microneedle is disclosed. (column 28, lines 8-19 of Allen et al.). In regard to claims 16-17, 20-21, 23, and 30, a sensor inside the microneedle can detect glucose with glucose oxidase. (column 7, line 66 to column 8, line 29 of Allen et al.). In regard to claim 25, there is a hole disclosed in the side of the microneedle. (column 6, lines 42-51 of Allen et al.). In regard to claims 13 and 26, there are transport control methods such as removable barriers and a material to modulate the flow. (column 7, lines 47-60 of Allen et al.). In regard to claims 38-40 and 42-44, the microneedle can be essentially metal. (column 13, lines 29-44 of Allen et al.) or hollow (column 11, lines 49-65 of Allen et al.).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3-5, 7, 29, and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,334,856 to Allen et al. as applied to claims 2, 27, and 32, and further in view of in view of U.S. Patent 5,364,374 to Morrison et al. (cited by Applicant). Allen et al. does not teach that the collection chamber is a standard or Luer-lock syringe. Allen et al. teaches that the device can be used for removing samples. (column 17, line 60 to column 18, lines 7 of Allen et al.). Allen does teach that the flow of molecules through the microneedle can occur based on diffusion, capillary action, or induced by conventional mechanical pumps or non-mechanical driving forces. Allen et al. provides a clear suggestions that the flow of particles though the microneedle can occur through a variety of means. Allen et al. further suggests that the flow of particles can be into or out of the device. It is well known in the art that a syringe is a mechanical pump that induces a flow of particles when withdrawing fluid. Morrison et al. discloses a microneedle connected to a syringe as stated in column 2, lines 26-40. Such a mechanical pump is the type of flow inducing means that Allen et al. requires. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microneedle device of Allen et al. include a syringe as disclosed by Morrison et al. since Allen et al. implies that the flow of particles can be performed by mechanical pump means and Morrison et al. teaches such means.

6. Claims 3, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,334,856 to Allen et al. as applied to claim 2 and further in view of in view of U.S. Patent 4,703,761 to Rathbone et al. (cited by Applicant). Allen et al. does

not disclose that the collection chamber comprises an upper portion which is formed of a material which is deformable. Allen et al. teaches that the device can be used for removing samples. (column 17, line 60 to column 18, lines 7 of Allen et al.). Allen does teach that the flow of molecules through the microneedle can occur based on diffusion, capillary action, or induced by conventional mechanical pumps or non-mechanical driving forces. Allen et al. provides a clear suggestions that the flow of particles though the microneedle can occur through a variety of means. Allen et al. further suggests that the flow of particles can be into or out of the device. Rathbone et al. teaches in column 1, lines 34-42 that a procedure for drawing blood involves the use of a flexible plastic bulb which is connected to a collecting tube and is manually squeezed to create negative pressure for drawing the blood sample. This device operates in a manner similar to an eye dropper. Such a mechanical pump is the type of flow inducing means that Allen et al. requires. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microneedle device of Allen et al. include a syringe as disclosed by Rathbone et al. since Allen et al. implies that the flow of particles can be performed by mechanical pump means and Rathbone et al. teaches such means. In regard to claim 8, one-way gate valves can be used. (column 7, lines 47-60 of Allen et al.).

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,334,856 to Allen et al. as applied to claim 1, and further in view of International Application Publication WO 98/00193 to Eppstein (cited by Applicant). Allen et al. does

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not explicitly teach the use of glucose strip inside the collection chamber. Allen et al. discloses that the fluid can be assayed while in the collection chamber (column 17, lines 60-67 of Allen et al.). Allen et al. further teaches that glucose concentration can be determined. (column 7, line 66 to column 8, line 29 of Allen et al.). It is well known in the art that glucose strips are used to determine the amount of glucose in a patient's blood. Eppstein discloses that the fluid can be analyzed according to known methods such as various test strips for glucose. (page 13, lines 28-32 of Eppstein). The use of glucose strips is the type of method that Allen et al. refers to while monitoring glucose. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Allen et al. to include the use of glucose strips as disclosed by Eppstein since Allen teaches that analytes can be monitored in the collection chamber and Eppstein teaches such a method.

Response to Arguments

8. Applicant's arguments filed 12/26/2001 have been fully considered but they are not persuasive. The Applicant's claim invention includes microneedles that have a length between about 500-1000 microns. Yoshihiko teaches a micro-collecting device that is 495 microns which is about 500 microns, particularly in light of engineering and design tolerances. The Examiner would also like to note that although the Applicant has disclosed the 500-1000 micron lengths for the microneedles in the specifications (page 6, lines 21-24), the claimed invention departs away from the preferred

embodiment of the invention in an attempt to overcome the rejection based on the Yoshihiko reference.

9. Applicant's arguments with respect to the other rejections have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,312, 612 to Sherman et al. discloses a microneedle array to facilitate sampling with diameters in the range of 1-50 microns and lengths in the range of 50-200 microns. U.S. Patent Application Publication 2001/0053891 to Ackley discloses microneedle arrays where diameters range from 80-160 microns and lengths run from 100-1000 microns.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer
Assistant Examiner
Art Unit 3736
March 5, 2002



ERIC F. WINAKUR
PRIMARY EXAMINER